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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/628,984	07/28/2003	Guohua Chen	ARC 3119 R1	7536

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EXAMINER	
ARNOLD, ERNST V	
ART UNIT	**PAPER NUMBER**
1616	

SHORTENED STATUTORY PERIOD OF RESPONSE	MAIL DATE	DELIVERY MODE
3 MONTHS	03/16/2007	PAPER

Please find below and/or attached an Office communication concerning this application or proceeding.

If NO period for reply is specified above, the maximum statutory period will apply and will expire 6 MONTHS from the mailing date of this communication.

Office Action Summary	Application No.	Applicant(s)	
	10/628,984	CHEN ET AL.	
	Examiner	Art Unit	
	Ernst V. Arnold	1616	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *21 December 2006*.

2a)☐ This action is **FINAL**. 2b)☒ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *1-84* is/are pending in the application.

4a) Of the above claim(s) *21-27 and 49-83* is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *1-20,28-48 and 84* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☒ The drawing(s) filed on *28 July 2003* is/are: a)☒ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☒ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☒ Information Disclosure Statement(s) (PTO/SB/08) Paper No(s)/Mail Date *9/15/03; 8/9/06*.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____ .
5) ☐ Notice of Informal Patent Application
6) ☐ Other: _____.

DETAILED ACTION

Claims 1-84 are pending.

The Examiner acknowledges Applicant's response to the restriction requirement filed on 10/27/06. Applicant elected the invention of Group I without traverse and elected in response to the species election requirement, the species drawn to the composition having poly(D,L-lactide-co-glycolides) (PLGAs) as a polymer matrix, benzyl alcohol as the solvent, and human growth hormone as the beneficial agent. The Examiner is expanding the search to any beneficial agent. The claims encompassing the elected species include claims 1-20, 28-48, and 84. The claims will be examined as they read upon the elected subject matter. Claims 21-27, 49-83 are withdrawn from consideration as being drawn to non-elected subject matter.

Claim Rejections - 35 USC § 112

The following is a quotation of the first paragraph of 35 U.S.C. 112:

> The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

Claims 1-20, 28-48, and 84 are rejected under 35 U.S.C. 112, first paragraph, because the specification, while being enabling for a composition comprising a polymer matrix comprising PGLA polymers, benzyl alcohol and mixtures of benzyl alcohol and benzyl benzoate it does not reasonably provide enablement for an injectable depot composition as claimed. The specification does not enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the invention commensurate in scope with these claims without an undue amount of experimentation.

The factors to be considered in determining whether a disclosure meets the enablement requirement of 35 U.S.C. 112, first paragraph, have been described in *In re Wands*, 8 USPQ2d 1400 (Fed. Cir. 1988). Among these factors are: 1) scope or breadth of the claims; 2) nature of the invention; 3) relative level of skill possessed by one of ordinary skill in the art; 4) state of, or the amount of knowledge in, the prior art; 5) level or degree of predictability, or a lack thereof, in the art; 6) amount of guidance or direction provided by the inventor; 7) presence or absence of working examples; and 8) quantity of experimentation required to make and use the claimed invention based upon the content of the supporting disclosure. When the above factors are weighed, it is the Examiner's position that one skilled in the art could not practice the invention without undue experimentation.

1) Scope or breadth of the claims

The claims are broader in scope than the enabling disclosure. The specification merely discloses, without more, that depot gels can be prepared with PGLA polymers (Examples 1-19). However, Applicant is purporting to use all bioerodible, biocompatible polymers or all solvents having a miscibility in water of less than 7% at 25 C and all beneficial agents.

2) Nature of the invention

The nature of the invention is directed to an injectable gel composition comprising a plurality of bioerodible, biocompatible polymers, solvent and a beneficial agent.

3) Relative level of skill possessed by one of ordinary skill in the art

The relative level of skill possessed by one of ordinary skill in the art of medical research is relatively high, as a majority of lead investigators directing scientific research and development in this particular technological area possess an M.D. and/or a Ph.D. in a scientific

discipline such as organic synthetic chemistry, medicinal chemistry, biochemistry, pharmacology, biology or the like.

4) State of, or the amount of knowledge in, the prior art

The art teaches a pharmaceutical composition in the form of a hydrophobic or hydrophilic gel comprising poly(lactide-co-glycolide), polylactide etc...and combination thereof, a penetration enhancer such as polyethylene glycol, benzyl alcohol and polypeptide growth factors (Cleary et al. (US 2003/0027833 Filed on May 7, 2002; Claims 1, 8, 10, 14-16, 20, 26 and 27, for example). Cleary et al. define gels as semisolid, suspension-type systems (Page 6, [0069]).

5) Level or degree of predictability, or a lack thereof, in the art

6) Amount of guidance or direction provided by the inventor

Applicant was required to provide in the specification additional guidance and direction with respect to how use the claimed subject matter in order for the application to be enabled with respect to the full scope of the claimed invention. Although the instant specification discloses compositions comprised of various molecular weight PGLA, benzyl alcohol and a beneficial agent, it remains silent on all bioerodible, biocompatible polymers or all solvents having a miscibility in water of less than 7% at 25 C or all beneficial agents dissolved or dispersed in the gel. Would hydroxyapatite or keratin, two bioerodible biocompatible polymers, be plasticized by the solvent to form a gel?

7) Presence or absence of working examples

The specification fails to provide scientific data and working embodiments with respect to all bioerodible, biocompatible polymers or all solvents having a miscibility in water of less

than 7% at 25 C or all beneficial agents dissolved or dispersed in the gel. The specification teaches PGLA polymers, benzyl alcohol as the solvent and human growth hormone or bupivacaine as the beneficial agent (See Pages 48-52, Examples 1-6 for example).

8) Quantity of experimentation required to make and use the claimed invention based upon the content of the supporting disclosure

One of ordinary skill in the art would have to conduct a myriad number of experiments comprising first testing whether or not all bioerodible, biocompatible polymers are plasticized to form a gel in a plurality of solvents having a miscibility in water of less than 7% at 25 C, which probably depends on the amount of polymer added thus adding another level of complexity to the experiments, and then adding a beneficial agent. As a result, one of ordinary skill in the art would be required to conduct an undue amount of experimentation to reasonably and accurately determine whether an injectable depot composition can be made with all bioerodible, biocompatible polymers plasticized to form a gel in a plurality of solvents having a miscibility in water of less than 7% at 25 C with all beneficial agents.

Genetech, 108 F.3d at 1366 states that "a patent is not a hunting license. It is not a reward for search, but compensation for its successful conclusion" and "patent protection is granted in return for an enabling disclosure of an invention, not for vague intimations of general ideas that may or may not be workable."

Claim Rejections - 35 USC § 112

The following is a quotation of the second paragraph of 35 U.S.C. 112:

> The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

Claims 1, 3-20, 28-48, and 84 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention. Claims 1, 3, 28-31 and 84 recite: " broad". It is unclear to the Examiner the metes and bounds of "broad". The term " broad " is a relative term, which renders the claim indefinite. The term " broad " is not defined by the claim, the specification does not provide a standard for ascertaining the requisite degree, and one of ordinary skill in the art would not be reasonably apprised of the scope of the invention. Claims 4-20 and 32-48 are rejected as being indefinite because they are dependent on an indefinite base claim. The Examiner will interpret the claim as it reads on any molecular weight.

Claims 20 and 48 recite the limitation "wherein the aromatic acid is benzyl alcohol". There is insufficient antecedent basis for this limitation in the claim. There is no aromatic acid in claims 19 or 47. The Examiner will examine the claim as it reads on benzyl alcohol.

Claim Rejections - 35 USC § 102

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

> A person shall be entitled to a patent unless –
>
> (a) the invention was known or used by others in this country, or patented or described in a printed publication in this or a foreign country, before the invention thereof by the applicant for a patent.
>
> (e) the invention was described in (1) an application for patent, published under section 122(b), by another filed in the United States before the invention by the applicant for patent or (2) a patent granted on an application for patent by another filed in the United States before the invention by the applicant for patent, except that an international application filed under the treaty defined in section 351(a) shall have the effects for purposes of this subsection of an application filed in the United States only if the international application designated the United States and was published under Article 21(2) of such treaty in the English language.

Claims 1, 4, 7-9 and 12-20 are rejected under 35 U.S.C. 102(a) and 35 U.S.C. 102(e) as being anticipated by Dunn et al. (WO 02/38185).

Dunn et al. discloses a composition comprising a biodegradable polyester, an organic solvent, and a beneficial agent (claim 1). The composition is taught to be injectable (example 3) The polymer can be a poly(lactide-co-glycolide) or polylactide or polyglcolide or combinations thereof (claims 2-4), and is present in amounts commensurate with instant claims (claim 5, examples 2 and 3). The molecular weight is also commensurate with that of instant claims, for example, 6,000 daltons (example 2). The solvent may be benzyl alcohol, benzyl benzoate, or a mixture thereof (claim 7), and is present in amounts commensurate with that of instant claims (claim 11, examples 2 and 3). The beneficial agent is taught to be in a suspension (examples 2 and 3), which is understood to mean that it is in the form of dispersed particles, which the examiner interprets to read on a gel. In example 3, an additional PEG-poly(lactide-co-glycolide) block copolymer is added. The reference further teaches a kit (claims 38- 45), containing the composition of the invention, commensurate in scope with instant claims in that the beneficial agent is in a separate container from the other agents.

Claim Rejections - 35 USC § 102

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

> A person shall be entitled to a patent unless –
>
> (b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

Claims 1, 4, 7-9 and 12-20 are rejected under 35 U.S.C. 102(b) as being anticipated by Billot et al. (US 5,540,937) as evidenced by the definition of gel from Answers.com.

Billot et al. disclose a formulation of a composition comprised of LHRH hormone, a polypeptide, dispersed in a water insoluble polymer or copolymer matrix for the prolonged release of the hormone and methods of making the composition (Claims 1 and 18-20). The hormone is dispersed in a second solvent, such as benzyl alcohol, while the material intended to form the matrix, polylactic acid, poly(lactide-glycolide), polylactides, poly(lactide-glycolic acid) etc..., is dissolved in the first solvent and the two phases obtained are mixed in order to obtain the organic phase, with a viscosity between about 0.01 and 10 Pa.s., suspended in the aqueous phase (Claims 1-7). It is the Examiner's position that this reads on a gel. (Gel: A colloid in which the disperse phase combines with the dispersion medium to produce a semisolid material. Answers.com) The matrix can comprise at least two types of polymers or copolymers (claim 14) and can be the same type but differ from each other in their ratios of constituent monomer units and or in their molecular masses (Claims 15) and can comprise a mixture of tow poly(DL-lactide-glycolide) polymers (Claim 16). It is the Examiner's position that Billot et al. disclose a composition that can be injectable comprising a plurality of PGLA polymers, benzyl alcohol and a beneficial agent simultaneously together and thus reads on instant claims 1, 4, 7-9 and 12-20. Billot et al. teach formulations comprising at least two types of microspheres differing by the composition of the matrices; such as the ratios of constituent monomer units and/or in the molecular masses and wherein in release is prolonged for a time equaling or exceeding 6 months (Claims 18-20).

Billot et al. teach a composition comprising 360 mg of poly(DL-lactide-glycolide) 75-25 and 40 mg of poly(DL-lactide-glycolide) 50-50 dissolved in THF to which 16.7 mg of LHRH is added. The solvent was evaporated and the dry residue was dissolved in dichloromethane to

obtain a suspension, which was injected into 500 ml of water containing 1% polyvinyl alcohol (Column 11, lines 1-12).

Claim Rejections - 35 USC § 102

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

> A person shall be entitled to a patent unless –
>
> (e) the invention was described in (1) an application for patent, published under section 122(b), by another filed in the United States before the invention by the applicant for patent or (2) a patent granted on an application for patent by another filed in the United States before the invention by the applicant for patent, except that an international application filed under the treaty defined in section 351(a) shall have the effects for purposes of this subsection of an application filed in the United States only if the international application designated the United States and was published under Article 21(2) of such treaty in the English language.

Claims 1, 4, 7-9 and 12-20 are rejected under 35 U.S.C. 102(e) as being anticipated by Cleary et al. (US 2003/0027833 Filed on May 7, 2002).

Cleary et al. disclose a pharmaceutical composition, that can be injectable, in the form of a hydrophobic or hydrophilic gel comprising poly(lactide-co-glycolide), polylactide etc...and combination thereof, a penetration enhancer such as polyethylene glycol, benzyl alcohol and polypeptide growth factors thus meeting the limitation of instant claims 1, 4, 7-9 and 12-20 (Claims 1, 8, 10, 14-16, 20, 26 and 27, for example). Cleary et al. define gels as semisolid, suspension-type systems (Page 6, [0069]).

Claim Rejections - 35 USC § 103

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

> (a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are

such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.

The factual inquiries set forth in *Graham* **v.** *John Deere Co.*, 383 U.S. 1, 148 USPQ 459 (1966), that are applied for establishing a background for determining obviousness under 35 U.S.C. 103(a) are summarized as follows:

1. Determining the scope and contents of the prior art.
2. Ascertaining the differences between the prior art and the claims at issue.
3. Resolving the level of ordinary skill in the pertinent art.
4. Considering objective evidence present in the application indicating obviousness or nonobviousness.

Claims 1-20, 28-48 and 84 are rejected under 35 U.S.C. 103(a) as being unpatentable over Billot et al. (US 5,540,937) in view of Dunn et al. (WO 02/38185).

Applicant claims an injectable gel composition comprising a plurality of bioerodible, biocompatible polymers, solvent and a beneficial agent.

Determination of the scope and content of the prior art

(MPEP 2141.01)

The reference of Billot et al. and Dunn et al. are discussed in detail above and that discussion is hereby incorporated by reference.

Ascertainment of the difference between the prior art and the claims

(MPEP 2141.02)

1. Billot et al. do not expressly teach a composition comprising low molecular weight, medium molecular weight and high molecular weight bioerodible biocompatible polymers that delivers the beneficial agent systemically in a controlled manner over a duration of one year.

2. Billot et al. do not expressly teach a kit.

Finding of prima facie obviousness

Rational and Motivation (MPEP 2142-2143)

1. It would have been obvious to one of ordinary skill in the art at the time the claimed invention was made to make the composition of Billot et al. with low molecular weight, medium molecular weight and high molecular weight bioerodible biocompatible polymers, in the specified molecular weight ranges and produce the instant invention.

One of ordinary skill in the art would have been motivated to do this because Billot et al. teach using more than one molecular weight polymer in the composition and it is just a matter of judicious selection of the molecular weights of the polymers and routine optimization of the composition by one of ordinary skill in the art. Such compositions would have bimodal or multimodal molecular weight distributions. Billot et al. teaches release of greater than 6 months which can read on a duration of one year.

2. . It would have been obvious to one of ordinary skill in the art at the time the claimed invention was made to make the composition of Billot et al. in the form of a kit as suggested by Dunn et al. and produce the instant invention.

One of ordinary skill in the art would have been motivated to do this because kits are easy to use for the practitioner in the art.

A reference is good not only for what it teaches by direct anticipation but also for what one of ordinary skill in the art might reasonably infer from the teachings. (*In re Opprecht* 12 USPQ 2d 1235, 1236 (Fed Cir. 1989); *In re Bode* 193 USPQ 12 (CCPA) 1976).

In light of the forgoing discussion, the Examiner concludes that the subject matter defined by the instant claims would have been obvious within the meaning of 35 USC 103(a).

From the teachings of the references, it is apparent that one of ordinary skill in the art would have had a reasonable expectation of success in producing the claimed invention. Therefore, the invention as a whole was *prima facie* obvious to one of ordinary skill in the art at the time the invention was made, as evidenced by the references, especially in the absence of evidence to the contrary.

Double Patenting

The nonstatutory double patenting rejection is based on a judicially created doctrine grounded in public policy (a policy reflected in the statute) so as to prevent the unjustified or improper timewise extension of the "right to exclude" granted by a patent and to prevent possible harassment by multiple assignees. A nonstatutory obviousness-type double patenting rejection is appropriate where the conflicting claims are not identical, but at least one examined application claim is not patentably distinct from the reference claim(s) because the examined application claim is either anticipated by, or would have been obvious over, the reference claim(s). See, e.g., *In re Berg*, 140 F.3d 1428, 46 USPQ2d 1226 (Fed. Cir. 1998); *In re Goodman*, 11 F.3d 1046, 29 USPQ2d 2010 (Fed. Cir. 1993); *In re Longi*, 759 F.2d 887, 225 USPQ 645 (Fed. Cir. 1985); *In re Van Ornum*, 686 F.2d 937, 214 USPQ 761 (CCPA 1982); *In re Vogel*, 422 F.2d 438, 164 USPQ 619 (CCPA 1970); and *In re Thorington*, 418 F.2d 528, 163 USPQ 644 (CCPA 1969).

A timely filed terminal disclaimer in compliance with 37 CFR 1.321(c) or 1.321(d) may be used to overcome an actual or provisional rejection based on a nonstatutory double patenting ground provided the conflicting application or patent either is shown to be commonly owned with this application, or claims an invention made as a result of activities undertaken within the scope of a joint research agreement.

Effective January 1, 1994, a registered attorney or agent of record may sign a terminal disclaimer. A terminal disclaimer signed by the assignee must fully comply with 37 CFR 3.73(b).

Claims 1, 4, 7-11, 12-20 and 84 are provisionally rejected on the ground of nonstatutory obviousness-type double patenting as being unpatentable over claims 1-3, 5, 7, 8, 10, 17, 18, and 113 of copending Application No. 10/701,939. Although the conflicting claims are not identical, they are not patentably distinct from each other because all the composition components are the

same it the instant composition would have the specified duration of time of sustained beneficial agent delivery. The same wt % of the polymers are taught and the same solvents are taught. One of ordinary skill in the art would immediately recognize the obvious variation.

Claims 1, 4, 7-9 and 12-20 are provisionally rejected on the ground of nonstatutory obviousness-type double patenting as being unpatentable over claims 1, 2, 6-12, 15, 16, 18, and 19 of copending Application No. 10/295,527. Although the conflicting claims are not identical, they are not patentably distinct from each other because the beneficial agent instantly recited encompasses beneficial polypeptides. The same aromatic alcohol solvents are taught and the same wt % of polymers are taught. One of ordinary skill in the art would immediately recognize the obvious variation.

Claims 1, 4, 7-9, 12-20 and 84 are provisionally rejected on the ground of nonstatutory obviousness-type double patenting as being unpatentable over claims 1, 2-6, 14-16, 18, 21, 22, 24, 27, 28, 29, 34-36, 38, 40-43, 51, 52, 57-59 and 105 of copending Application No. 10/606,969. Although the conflicting claims are not identical, they are not patentably distinct from each other because all the composition components are the same and the instant composition encompasses low molecular weight polymers. The Examiner notes a that copending claim 3 states "wherein the aromatic alcohol is not benzyl alcohol" but copending claim 6 defines benzyl alcohol. Be that as it may, the copending application teaches the same composition of bioerodable polymers, solvents (benzyl alcohol), wt % polymers and kits of the composition. One of ordinary skill in the art would immediately recognize the obvious variation.

Claims 1, 4, 7, 8, and 12-20 are provisionally rejected on the ground of nonstatutory obviousness-type double patenting as being unpatentable over claims 1-12 of copending

Application No. 11/554,540. Although the conflicting claims are not identical, they are not patentably distinct from each other because all the composition components are the same and the instant composition encompasses low molecular weight polymers. The copending application teaches the same composition of bioerodable polymers, solvents (benzyl alcohol), and implantable gels with beneficial agents dissolved or dispersed in the gel. One of ordinary skill in the art would immediately recognize the obvious variation.

Claims 1, 4, 7, 8, and 12-20 are provisionally rejected on the ground of nonstatutory obviousness-type double patenting as being unpatentable over claims 1-3, 5-12 and 15-17 of copending Application No. 10/857,609. Although the conflicting claims are not identical, they are not patentably distinct from each other because all the composition components are the same and the instant composition encompasses low molecular weight polymers. The copending application teaches the same composition of bioerodable polymers, solvents (benzyl alcohol), and implantable gels with beneficial agents dissolved or dispersed in the gel. The time of release is inherent in the composition. One of ordinary skill in the art would immediately recognize the obvious variation.

The Examiner has made five double patenting rejections. The Examiner requests that Applicant assist the Examiner in identifying other double patenting issues that might arise during prosecution.

This is a provisional obviousness-type double patenting rejection because the conflicting claims have not in fact been patented.

Conclusion

No claims are allowed.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Ernst V. Arnold whose telephone number is 571-272-8509. The examiner can normally be reached on M-F (6:15 am-3:45 pm).

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Johann Richter can be reached on 571-272-0646. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

Ernst Arnold
Patent Examiner
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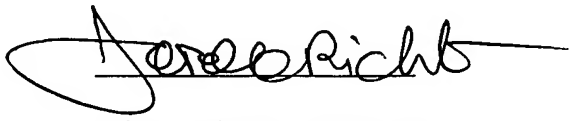
Art Unit 1616



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